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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,522	11/28/2001	Cohava Gelber	3828-4000US1	9860

7590 07/29/2004
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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,522

Applicant(s)

GELBER, COHAVA

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-37, 51-56, 65-69 and 73-85 is/are pending in the application. WR
- 4a) Of the above claim(s) 1-12, 14-17, 21-24, 30-37 and 51-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 25-29, 65-69, 73-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 18, 19, 25, 65, 66, 68, 69, 73-77, 80 have been amended and claims 81-85 have been added. It is noted that claim 13 is not presented and will be assumed canceled.
2. Claims 1-12, 14-17, 21-24, 30-32, 34-37, 51-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 5.
3. Claims 18-20, 25-29, 65-69, 73-85 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

5. The rejection of claims 18-20, 25-29, 65-74 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
6. The rejection of claims 19-20, 25-29, 75-80 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the declaration of biological deposit and meeting all assurances.

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7. The rejection of claims 18-20, 25-29, 65-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 18, 65, 70, under 35 U.S.C. 102(b) as being anticipated by Lloyd et al (Int. J. Cancer 71:842-850, 1997, IDS paper #3) is withdrawn in view of the amendments to the claims.

9. The rejection of claims 18-20, 25-26, 65-74 under 35 U.S.C. 103(a) as being unpatentable over Lloyd et al (Int J. Cancer 71:842-850, 1997, IDS paper #3) as applied to claim above, and further in view of Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pp 319-329, 626-631, 1988, IDS #3) is withdrawn in view of the amendment to the claims.

Response to Arguments

10. The rejection of claims 18-20, 25-29, 65-69, 73-80 and newly added claims 81-85 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 5/10/04 has been carefully considered but is deemed not to be persuasive. The response states that that correlation between binding of a monoclonal antibody and its ability to reduce tumor size and increase survival had been reported in the art as of the filing date and cites Ozaki et al as teaching an anti-HM1.24 antibody for therapy (see page 18-10 of response). In response to this argument, while

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some antibodies may be used for therapy when the antigen is well characterized as in the Ozaki case, the Ozaki antibody acts through CDC actions and the antibody alone does not inhibit the cells as taught in the abstract as stated "cells was inhibited in vitro by anti-HM1.24 IgG-mediated complement-dependent cytotoxicity, but not by the antibody alone". Thus, the antibody acts through the CDC mechanism and not all antibodies act through this mechanism and in fact the specification does not disclose the claimed antibody acting in any inhibition or killing of the myeloma or ovarian cells as stated in the rejection either conjugated or unconjugated. In addition, the response does not address the prior art demonstrating undue experimentation of going from in vitro to in vivo data as evidenced from Freshney, Dermer and Gura.

The response states that Krueger et al demonstrates the VAC69 antibody, which is disclosed in the specification, does trigger cytotoxicity in vivo (see page 19 of response). In response to this argument, the specification does not disclose the VAC69 antibody at all. It is unclear if the VAC69 antibody is the same as the MA69 antibody disclosed in the specification or if it is the same as that deposited as ATCC PTA-450.

Thus, because of the lack of guidance in the specification and the unpredictability in the prior art, in weighing the factors to be considered in determining whether or not the practice of a claimed invention would require "undue" experimentation, as set forth in *In re Wands* (8 USPQ 2d at 1404), the weight of the analysis clearly favors a finding of "undue" experimentation.

Conclusions

11. No Claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ^{JEFFREY SIEW}~~Christina Chan~~, can be reached at (571) 272-⁰⁷⁸⁷~~0841~~.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The

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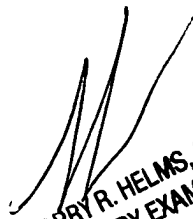
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faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER